UNITED STATES DISTRICT COURT FOR THE
WESTERN DISTRICT OF MISSOURI
SOUTHERN DIVISION

TIM ROSENAUER, on behalf of himself and all others similarly situated, Plaintiff, vs. SANOFI-AVENTIS U.S. LLC, SANOFI US SERVICES INC., CHATTEM, INC., and BOEHRINGER INGELHEIM PHARMACEUTICALS, INC., Defendants.	Case No. CLASS ACTION JURY TRIAL DEMANDED

COMPLAINT

Plaintiff Tim Rosenauer, on behalf of himself and all others similarly situated, for his action against Defendants Sanofi-Aventis U.S. LLC, Sanofi US Services Inc., and Chattem, Inc. (collectively "Sanofi" or "Sanofi Defendants"), and Boehringer Ingelheim Pharmaceuticals, Inc. ("Boehringer") states and alleges the following:

1. Zantac—the brand-name version of the generic drug ranitidine—is used to treat gastrointestinal conditions such as acid indigestion, heartburn, sour stomach, and gastroesophageal reflux disease. As recently as 2018, Zantac was widely used and remained one of the most popular acid-reducers in the United States, with sales of over $100 million annually.

2. But Zantac's prodigious sales were possible only because of a deception perpetrated by the drug's manufacturers on consumers who have purchased Zantac since it hit the market in 1983. The producers of Zantac, including the Sanofi Defendants, never disclosed to consumers that the drug has a critical defect: When ingested, Zantac produces in the human body high quantities of N-Nitrosodimethylamine (NDMA), a potent carcinogen.

3. Recent scientific testing conducted by Valisure LLC and ValisureRX LLC (collectively "Valisure"), as described in their Citizen Petition to the FDA filed on Septebmer 13, 2019, "has detected extremely high levels of NDMA in all lots [of ranitidine] tested, across multiple manufacturers of ranitidine products," including Zantac.

4. The tests conducted by Valisure show that ranitidine can react with itself in standard analysis conditions at high efficiency to produce NDMA at dangerous levels well in excess of the permissible daily intake limit for this probable carcinogen.

5. The FDA has announced a permissible intake limit of 96 ng of NDMA per day. Valisure's testing, detected 2,511,469 ng of NDMA per 150 mg tablet of Zantac, i.e., more than 26,000 times the amount that can be safely ingested daily.

6. The typical recommended dose of ranitidine for therapy of peptic ulcer disease in adults is 150 mg twice daily or 300 mg once nightly for 4 to 8 weeks, and maintenance doses of 150 mg once daily. Moreover, chronic use of the drug is common for therapy of heartburn and indigestion.

7. Thus, a typical consumer who is taking Zantac over the course of eight weeks to treat peptic ulcer disease is exposed to more than 280,000,000 ng (or 0.28 grams) of NDMA. And a consumer who takes a 150 mg maintenance dose of Zantac once daily is

exposed to 889,000,000 ng (0.889 grams) of NDMA over the course of a year, in comparison to the FDA's permissible intake limit of NDMA is 96 ng per day, which translates to just 0.000034 grams per year.

8. In addition to the FDA-recommended testing described above, when Zantac was tested in conditions simulating the human stomach, the quantity of NDMA detected was as high as 304,500 ng per tablet—3,171 times more than the amount that can be safely ingested daily.

9. Sanofi has owned the U.S. rights to over-the-counter Zantac since about January 2017, and has manufactured and distributed the drug during that period. Previously, Defendant Boehringer owned the U.S. rights to Zantac and manufactured and distributed the drug from about October 2006 to January 2017.

10. Both Sanofi and Boehringer knew or had reason to know that Zantac exposes users to unsafe levels of the carcinogen NDMA: During the period that Sanofi and Boehringer manufactured and distributed Zantac, numerous scientific studies were published showing, among other things, that ranitidine (the generic equivalent of Zantac) forms NDMA when placed in drinking water and that a person who consumes ranitidine has a 400-fold increase of NDMA concentration in their urine.

11. Despite the weight of scientific evidence showing that Zantac exposed users to unsafe levels of the carcinogen NDMA, neither Sanofi nor Boehringer disclosed this risk to consumers. Had Defendants disclosed that Zantac results in unsafe levels of NDMA in the human body, Plaintiff, like any other reasonable person, would not have purchased and consumed Zantac.

12. Plaintiff previously purchased the over-the-counter version of Zantac. Plaintiff seeks to represent a class of those persons who purchased over-the-counter Zantac in the State of Missouri during the applicable statute of limitations period, including periods of tolling.

13. Had Plaintiff and the class known that taking Zantac would expose them to high levels of the carcinogen NDMA, they would not have purchased the drug.

14. Defendants' failure to disclose this material information to Plaintiff and the class constitutes fraudulent concealment under Missouri law, violates implied warranties, and runs afoul of Missouri's consumer-protection laws, including the Missouri Merchandising Practices Act ("MMPA").

PARTIES

15. Plaintiff Tim Rosenauer is a citizen of the State of Missouri and resides in Lebanon, Laclede County, Missouri.

16. Mr. Rosenauer first purchased over-the-counter Zantac in approximately 1995 at either a Sam's Club or Walgreens in Missouri; he took the drug consistently for the ensuing 24 years.

17. Mr. Rosenauer purchased over-the-counter Zantac that was manufactured and distributed by Defendant Boehringer and by the Sanofi Defendants.

18. If Mr. Rosenauer had known that taking Zantac would have exposed him to unsafe quantities of NDMA, then he would not have purchased or used the drug.

19. Defendant Sanofi-Aventis U.S. LLC is a Delaware limited liability corporation with a principal place of business at 55 Corporate Drive, Bridgewater, New Jersey 08807, and is a wholly owned subsidiary of the French company Sanofi.

20. Defendant Sanofi US Services Inc. is a Delaware corporation with a principal place of business at 55 Corporate Drive, Bridgewater, New Jersey 08807, and is a wholly owned subsidiary of the French company Sanofi.

21. Defendant Chattem, Inc. is a Tennessee corporation with a principal place of business at 1715 West 38th Street Chattanooga, Tennessee 37409, and is a wholly owned subsidiary of the French company Sanofi.

22. Defendants Sanofi-Aventis U.S. LLC, Sanofi US Services Inc., and Chattem, Inc. (collectively "Sanofi" or "Sanofi Defendants") have controlled the U.S. rights to Zantac from about January 2017 to the present, manufacturing and distributing the drug in the United States during that period.

23. Defendant Boehringer Ingelheim Pharmaceuticals, Inc. ("Boehringer") is a Delaware corporation with a principal place of business at 900 Ridgebury Road, Ridgefield, Connecticut 06877, and is a subsidiary of the German company Boehringer Ingelheim Corporation. Boehringer owned the U.S. rights to Zantac from about October 2006 to January 2017, manufacturing and distributing the drug in the United States during that period.

JURISDICTION AND VENUE

24. This Court has jurisdiction under 28 U.S.C. § 1332(d), which provides federal district courts with original jurisdiction over any civil action in which the matter in controversy exceeds the sum or value of $5 million, exclusive of interests and costs, and is a

class action in which any member of a class of plaintiffs is a citizen of a state different from any defendant.

25. The Court has personal jurisdiction over each Defendant because each Defendant has transacted business, maintained substantial contacts, and/or committed overt acts in this District. Defendants' unlawful conduct has injured persons residing in, located in, or doing business throughout this District.

26. Venue is proper in this judicial district pursuant to 28 U.S.C. § 1391(b) and (c) because each Defendant transacts business in, is found in, and/or has agents in the Western District of Missouri, and because some of the actions giving rise to this complaint took place within this district.

27. Assignment to the Southern Division of this Court is proper pursuant to Local Rule 3.2 because all defendants reside outside of the district and Plaintiff resides in Laclede County Missouri.

FACTUAL ALLEGATIONS

28. Zantac was developed by Glaxo—now GlaxoSmithKline—and approved for prescription use by the FDA in 1983. The drug belongs to a class of medications called histamine H2-receptor antagonists (or H2 blockers), which decrease the amount of acid produced by the stomach and are used to treat gastric ulcers, heartburn, acid indigestion, sour stomach, and other gastrointestinal conditions.

29. Zantac was a wildly successful drug, reaching $1 billion in total sales in December 1986. As one 1996 article put it, Zantac became "the best-selling drug in history as a result of a shrewd, multifaceted marketing strategy that . . . enabled the product to

dominate the acid/peptic marketplace." Significantly, the marketing strategy that led to Zantac's success emphasized the purported safety of the drug.

30. Zantac became available without a prescription in 1996, and generic versions of the drug (ranitidine) became available the following year. Nonetheless, Zantac sales have remained strong over time. As recently as 2018, Zantac was one of the top 10 antacid tablet brands in the United States, with sales of Zantac 150 totaling $128.9 million—a 3.1% increase from the previous year.

31. Over the past 20 years, the rights to Zantac in the U.S. have changed hands several times. Defendant Boehringer acquired the U.S. rights to over-the-counter Zantac in late 2006 and manufactured and sold the drug in the United States—including in Missouri—from approximately January 2007 to January 2017.

32. The Sanofi Defendants acquired the U.S. rights to over-the-counter Zantac in approximately January 2017 and have since that time been manufacturing and selling the drug in the United States, including in Missouri.

33. NDMA is a semi-volatile organic chemical that forms in both industrial and natural processes. It is a member of N-nitrosamines, a family of potent carcinogens.

34. The dangers that NDMA poses to human health have long been recognized. A news article published in 1979 noted that "NDMA has caused cancer in nearly every laboratory animal tested so far" and subsequent publications over the years have reiterated its carcinogenic effects. *See* Jane Brody, *Bottoms Up: Alcohol in moderation can extend life*, THE GLOBE AND MAIL (CANADA) (Oct. 11, 1979); *see* Rudy Platiel, *Anger grows as officials unable to trace poison in reserve's water*, THE GLOBE AND MAIL (CANADA) (Jan. 6, 1990) (reporting that residents of Six Nations Indian Reserve "have been advised not to

drink, cook or wash in the water because testing has found high levels of N-nitrosodimethylamine (NDMA), an industrial byproduct chemical that has been linked to cancer"); S.A. Kyrtopoulos, *DNA adducts in humans after exposure to methylating agents*, 405 MUTATION RESEARCH 135 (1998) (noting that "chronic exposure of rats to very low doses of NDMA gives rise predominantly to liver tumours, including tumours of the liver cells (hepatocellular carcinomas), bile ducts, blood vessels and Kupffer cells").

35. NDMA is no longer produced or commercially used in the United States, except for research.

36. Both the EPA and the International Agency for Research on Cancer ("IARC") have classified NDMA as a probable human carcinogen. And the World Health Organization has stated that scientific testing indicates that NDMA consumption is positively associated with either gastric or colorectal cancer and suggests that humans may be especially sensitive to the carcinogenicity of NDMA.

37. As early as 1980, consumer products containing unsafe levels of NDMA and other nitrosamines have been recalled by manufacturers, either voluntarily or at the direction of the FDA.

38. Most recently, beginning in the summer of 2018, there have been recalls of several generic drugs used to treat high blood pressure and heart failure—valsartan, losartan, and irbesartan—because the medications contained nitrosamine impurities that don't meet the FDA's safety standards, which provide that the intake of NDMA should be no more than 96 ng. The highest level of NDMA detected by the FDA in any of the valsartan tablets was 20.19 μg (or 20,190 ng) per tablet. In the case of valsartan, the NDMA was an

impurity caused by a manufacturing defect, and thus NDMA was present in only some products containing valsartan.

39. Zantac poses a greater safety risk than any of the recently recalled valsartan tablets. Applying the FDA-recommended GC/MS protocols for detecting NDMA—the same protocols used by the FDA to detect NDMA in valsartan—the level of NDMA in Zantac is 2,511,469 ng per Zantac tablet—124 times more than the highest amount detected in the recalled valsartan.

40. Moreover, the high levels of NDMA produced by Zantac are not caused by a manufacturing defect but rather are inherent to the molecular structure of ranitidine, the active ingredient in Zantac: "The ranitidine molecule contains both a nitrite and a dimethylamine ('DMA') group which are well known to combine to form NDMA." Thus, ranitidine produces NDMA by "react[ing] with itself," which means that every dosage and form of ranitidine, including Zantac, exposes users to NDMA.

41. During the time that Defendants manufactured and sold over-the-counter Zantac in the United States, the weight of scientific evidence showed that Zantac exposed users to unsafe levels of NDMA. Neither Sanofi nor Boehringer disclosed this risk to consumers on the drug's label—or through any other means—nor did Defendants report these risks to the FDA, despite being on notice of the risk.

42. Defendants concealed the Zantac–NDMA link from consumers in part by not reporting it to the FDA, which relies on drug manufacturers (or others, such as those who submit citizen petitions) to bring new information about an approved drug like Zantac to the agency's attention.

43. Manufacturers of an approved drug are required by regulation to submit an annual report to the FDA containing, among other things, new information regarding the drug's safety:

> The report is required to contain . . . [a] brief summary of significant new information from the previous year that might affect the safety, effectiveness, or labeling of the drug product. The report is also required to contain a brief description of actions the applicant has taken or intends to take as a result of this new information, for example, submit a labeling supplement, add a warning to the labeling, or initiate a new study.

21 C.F.R. § 314.81(b)(2).

44. The manufacturer's annual report also must contain "[c]opies of unpublished reports and summaries of published reports of new toxicological findings in animal studies and in vitro studies (e.g., mutageniticity) conducted by, or otherwise obtained by, the [manufacturer] concerning the ingredients in the drug product." 21 C.F.R. § 314.81(b)(2)(v).

45. Despite being required to do so, Defendants did not report to the FDA significant new information affecting the safety or labeling of Zantac.

46. Defendants never provided the relevant studies to the FDA, nor did they present to the FDA with a proposed disclosure noting the link between ranitidine and NDMA.

CLASS ACTION ALLEGATIONS

47. Plaintiff brings this action under Federal Rule of Civil Procedure 23(a) and (b)(3), on behalf of himself and the members of the following class during the statute of limitations period, plus appropriate tolling, applicable to each of his claims below (the "class period"):

> All individual residents of Missouri who purchased over-the-counter Zantac for personal, family, or household use during the class period.

48. Excluded from the class are each Defendant and any entity in which a Defendant has a controlling interest, as well as any Defendant's legal representatives, officers, directors, assignees, and successors.

49. Members of the class are so numerous that joinder of all members is impracticable. It is believed that the size of the class numbers in the hundreds of thousands. Class members are readily identifiable from information and records in the possession of Defendants and third-party pharmacies such as CVS, Walgreens, Walmart, and Sams Club.

50. Plaintiff's claims are typical of the claims of the members of the class. Plaintiff and all class members were damaged by the same wrongful conduct of Defendants: As a result of Defendants' failing to disclose that Zantac exposed users to unsafe levels of the carcinogen NDMA, Plaintiff and class members were misled into purchasing Zantac—a drug they otherwise would not have purchased. There are numerous remedies that can be substituted for Zantac.

51. Plaintiff will fairly and adequately protect and represent the interests of the class. The interests of Plaintiff are consistent with, and not antagonistic to, those of the other members of the class.

52. Plaintiff's counsel are experienced in the prosecution of class-action litigation.

53. Questions of law and fact common to the members of the class predominate over questions that may affect only individual class members because Defendants have acted on grounds generally applicable to the class, thereby making damages with respect to the class, as a whole, appropriate.

54. Questions of law and fact common to the Class include, but are not limited to:

a. Whether the Zantac sold by Defendants exposed Plaintiff and Class members to unsafe levels of the carcinogen NDMA;

b. Whether Defendants knew or had reason to know that Zantac exposes users to unsafe quantities of NDMA;

c. Whether Defendants acted to conceal from consumers that Zantac exposes users to unsafe quantities of NDMA;

d. Whether Defendants notified the FDA that Zantac exposes users to unsafe quantities of NDMA;

e. Whether Defendants attempted to gain approval from the FDA to change Zantac's label to add a warning that the drug exposes users to unsafe quantities of NDMA;

f. Whether Defendants acted to conceal from the FDA the link between Zantac and NDMA;

g. Whether Defendants' failure to disclose on Zantac's label (or elsewhere) that the drug produces high levels of the carcinogen NDMA was unfair, deceptive, fraudulent, or unconscionable;

h. Whether Defendants are liable to Plaintiffs and Class members for damages under state consumer-protection statutes;

i. When Defendants manufactured and sold Zantac in the United States;

j. Whether an injunction should be issued requiring Sanofi Defendants to disclose on Zantac labels that the drug exposes users to unsafe levels of NDMA; and

k. Whether Plaintiffs and Class members are entitled to attorneys' fees, prejudgment interest, and costs, and if so, in what amount.

55. Plaintiff and class members have all suffered harm and damages as a result of Defendants' unlawful and wrongful conduct. A class action is superior to other available methods for the fair and efficient adjudication of this controversy under Rule 23(b)(3). Such treatment will permit similarly situated persons to prosecute their common claims in a single forum simultaneously, efficiently, and without the unnecessary duplication of evidence, effort, or expense that numerous individual actions would engender. The benefits of proceeding through the class mechanism—including providing injured persons or entities a method for obtaining redress on claims that could not practicably be pursued individually—substantially outweigh potential difficulties in management of this class action.

56. Absent a class action, most members of the class would find the cost of litigating their claims to be prohibitive and will have no effective remedy at law.

57. The class treatment of common questions of law and fact also is superior to multiple individual actions or piecemeal litigation in that it conserves the resources of the courts and the litigants and promotes consistency and efficiency of adjudication.

58. Defendants have acted and failed to act on grounds generally applicable to Plaintiffs and the Class and require court imposition of uniform relief to ensure compatible standards of conduct toward the Class, thereby making appropriate equitable relief to the Class as a whole within the meaning of Rules 23(b)(1) and (b)(2).

TOLLING OF THE STATUTE OF LIMITATIONS AND ESTOPPEL

59. Within the period of any applicable statutes of limitation, Plaintiff and members of the class could not have discovered through the exercise of reasonable diligence that Defendants were not disclosing the high levels of the carcinogen NDMA produced by Zantac.

60. Plaintiff and the other class members did not discover, and did not know of, facts that would have caused a reasonable person to suspect that Defendants did not disclose the high levels of NDMA produced by Zantac. The information linking Zantac to NDMA was contained exclusively in articles that were published in scientific journals. The significance of these highly technical articles would not have been apparent to Plaintiff or class members.

61. Plaintiff and class members could not have reasonably discovered the true extent of Defendants' deception with regard to Zantac's safety until Valisure filed its citizen petition disclosing the extremely high levels of NDMA produced by Zantac.

62. For these reasons, all applicable statutes of limitation have been tolled by operation of the discovery rule.

63. All applicable statutes of limitation have also been tolled by Defendants' fraudulent concealment throughout the period relevant to this action of Zantac's producing high levels of the carcinogen NDMA.

64. Instead of disclosing to consumers the link between Zantac and the carcinogen NDMA, Defendants continued to manufacture and sell Zantac without disclosing this information on the drug's label or elsewhere.

65. Defendants were under a continuous duty to disclose to Plaintiff and the other class members the risk of NDMA exposure associated with Zantac.

66. Defendants knowingly, affirmatively, and actively concealed or recklessly disregarded the true risks of NDMA exposure associated with Zantac and never updated the drug's label to disclose this risk.

67. Based on the foregoing, Defendants are estopped from relying on any statutes of limitations in defense of this action.

COUNT 1

Violation of Missouri Merchandising Practices Act ("MMPA") (Mo. Rev. Stat. § 407.010, *et seq.*),

68. Plaintiff incorporates by reference the allegations contained in the preceding paragraphs of this complaint.

69. This claim is brought against all Defendants on behalf of residents of Missouri who are members of the class. The MMPA expressly provides for class action treatment of claims brought under it. *See* Mo. Rev. Stat. § 407.025.

70. The MMPA prohibits unfair methods of competition and unfair or deceptive acts or practices.

71. The acts and practices engaged in by Defendants, and described herein, constitute unlawful, unfair, and fraudulent business practices in violation of the MMPA.

72. Each Defendant is a "person" under the MMPA as defined at Mo. Rev. Stat. § 407.010(5).

73. Plaintiff and class members each purchased one or more Zantac products at primarily for personal, family, or household purposes.

74. Defendants' failure to disclose—by labeling or otherwise—the NDMA risk presented by Zantac constituted unlawful practices including deception, false promises, misrepresentation, or the concealment, suppression, or omission of material facts in connection with the sale, distribution, or advertisement of Zantac in violation of the MMPA.

75. Defendants misrepresented and omitted material facts regarding Zantac—specifically regarding its exposing consumers to NDMA—with an intent to mislead Plaintiff and class members.

76. Plaintiffs and class members had no way of knowing Defendants' representations regarding Zantac were false, misleading, and incomplete.

77. Defendants knew or should have known that their conduct violated the MMPA.

78. Defendants' conduct proximately caused injury to Plaintiffs and class members who purchased over-the-counter Zantac.

79. Plaintiff and class members were injured and suffered ascertainable loss, injury-in-fact, and/or actual damages as a proximate result of Defendants' conduct in that Plaintiff and class members—indeed, no rational person—would not have purchased Zantac had they known that the drug exposed them to high levels of NDMA.

80. Plaintiff and class members purchased Zantac, a product that was falsely represented, as stated above, in violation of the MMPA and as a result Plaintiff and class members economic damages in that the product they and other class members purchased was worth less than the product they thought that had purchased had Defendants' representations been true.

81. Defendants' unlawful practices including deception, false promises, misrepresentation, and concealment, suppression, or omission of material facts in connection with the sale, distribution, or advertisement of Zantac were outrageous because of Defendants' evil motive or conscious disregard or reckless indifference to the rights and safety of Plaintiff the class members.

82. As a result of Defendants' conduct alleged herein, the jury should be permitted to return a verdict of punitive damages under this Count 1 of the Complaint to punish Defendants and deter others from like conduct. The MMPA expressly provides for punitive damages. *See* Mo. Rev. Stat. § 407.025.

WHEREFORE, Plaintiff, individually and on behalf of similarly situated individuals, prays this Court enter judgment in his favor and against all Defendants as follows:

a. awarding an amount to be determined at trial by jury that will fairly compensate Plaintiff, individually and on behalf of similarly situated individuals, for the harms suffered,

b. awarding Plaintiff, individually and on behalf of similarly situated individuals, punitive damages in an amount sufficient to deter all Defendants and others from such conduct in the future, and

c. awarding Plaintiff, individually and on behalf of similarly situated individuals, their costs incurred herein, post-judgment interest, reasonable attorneys' fees, expenses and for such other and further relief as the Court may deem just and proper under the circumstances.

COUNT 2

Breach of Implied Warranty of Merchantability

83. Plaintiff incorporates by reference the allegations contained in the preceding paragraphs of this Complaint.

84. This claim is brought against all Defendants on behalf of residents of Missouri who are members of the class.

85. When Defendants sold Zantac to Plaintiff and the class members, the Zantac sold was not fit for its ordinary purpose in that it exposed persons who take the drug to high levels of the carcinogen NDMA.

86. Defendants knew or should have known that Zantac was not fit for its ordinary purpose.

87. Because Zantac was unfit for its ordinary purpose, Plaintiff and the other class members have been deprived of the benefit of their bargain.

WHEREFORE, Plaintiff, individually and on behalf of similarly situated individuals pray this Court enter judgment in its favor and against all Defendants as follows:

a. awarding an amount to be determined at trial by jury that will fairly compensate Plaintiff, individually and on behalf of similarly situated individuals, for the harms suffered,

b. awarding Plaintiff, individually and on behalf of similarly situated individuals, their costs incurred herein, post-judgment interest, and for such other and further relief as the Court may deem just and proper under the circumstances.

COUNT 3

Breach of Implied Warranty of Fitness for a Particular Purpose

88. Plaintiff incorporates by reference the allegations contained in the preceding paragraphs of this Complaint.

89. This claim is brought against all Defendants on behalf of residents of Missouri who are members of the class.

90. Defendants sold Zantac to Plaintiff and the class members.

91. Defendants knew or should have known at the time it sold Zantac to Plaintiff and the class members that the Zantac sold exposed persons who take the drug to high levels of the carcinogen NDMA.

92. When Defendants sold Zantac to Plaintiff and the class members, Zantac was not fit for its particular purpose for which it was sold in that it exposed persons who take the drug to high levels of the carcinogen NDMA.

93. Because Zantac was unfit for the particular purpose for which it was sold, Plaintiff and the class members have been deprived of the benefit of their bargain.

WHEREFORE, Plaintiff, individually and on behalf of similarly situated individuals pray this Court enter judgment in its favor and against all Defendants as follows:

a. awarding an amount to be determined at trial by jury that will fairly compensate Plaintiff, individually and on behalf of similarly situated individuals, for the harms suffered,

b. awarding Plaintiff, individually and on behalf of similarly situated individuals, their costs incurred herein, post-judgment interest, and for such other and further relief as the Court may deem just and proper under the circumstances.

COUNT 4

Fraudulent Concealment (under Missouri Common Law) Against the Sanofi Defendants

94. Plaintiff incorporates by reference the allegations contained in the preceding paragraphs of this Complaint.

95. This claim is brought against the Sanofi Defendants on behalf of residents of Missouri who are members of the Class.

96. The Sanofi Defendants sold Zantac to Plaintiff and the class members.

97. The Sanofi Defendants knew or should have known at the time it sold Zantac to Plaintiff and the class members that the Zantac sold exposed persons who take the drug to high levels of the carcinogen NDMA.

98. The Sanofi Defendants intentionally concealed that Zantac is defective and unsafe because it exposes consumers to high levels of the carcinogen NDMA.

99. The Sanofi Defendants affirmatively misrepresented to Plaintiffs and class members in advertising and other forms of communication, including standard and uniform material provided with the drug's packaging, that Zantac had no significant defects and was safe to consume.

100. The Sanofi Defendants knew about he defect in Zantac when they made these representations.

101. The Sanofi Defendants had a duty to disclose that Zantac contains a fundamental defect as alleged herein, because the defect created a risk to consumers' health.

102. At all relevant times, the Sanofi Defendants held out Zantac to be free from defects and to be safe for consumers. The Sanofi Defendants touted the many benefits and advantages of Zantac, but failed to disclose important facts related to the defect. This made the Sanofi Defendants' other statements about Zantac deceptive.

103. Plaintiff and the class members did not know of the defect in Zantac, and the Sanofi Defendants actively concealed the defect from them.

104. Plaintiff and the class members had no way of knowing that the Sanofi Defendants' representations were false, misleading, or incomplete. As consumers, Plaintiff and the class members did not, and could not, unravel the Sanofi Defendants' deception on their own. Rather the Sanofi Defendants intended to deceive Plaintiffs and the class members by concealing the true facts about Zantac exposing consumers to high levels of the carcinogen NDMA.

105. The Sanofi Defendants' false representations and omissions were material to consumers because they concerned a quality of Zantac—safety—that played a significant role in the value of Zantac to consumers.

106. The Sanofi Defendants had a duty to disclose the Zantac defect because the Sanofi Defendants knew that the defect was not known to or reasonably discoverable by Plaintiff or the class members.

107. Plaintiffs and the class members were unaware of the omitted materials facts referenced herein, and they would not have acted as they did if they had known of the

concealed or suppressed facts, in that they would not have purchased Zantac and would have taken other affirmative steps in light of the information concealed from them.

108. Because of the Sanofi Defendants' concealment and suppression of facts, Plaintiff and the class members sustained damages because no reasonable person would have purchased or consumed Zantac but for the Sanofi Defendants' actions.

109. The Sanofi Defendants' unlawful practices including deception, false promises, misrepresentation, and concealment, suppression, or omission of material facts in connection with the sale, distribution, or advertisement of Zantac were outrageous because of the Sanofi Defendants' evil motive or conscious disregard or reckless indifference to the rights and safety of Plaintiff the class members.

110. As a result of the Sanofi Defendants' conduct alleged herein, the jury should be permitted to return a verdict of punitive damages under this Count 4 of the Complaint to punish the Sanofi Defendants and deter others from like conduct.

WHEREFORE, Plaintiff, individually and on behalf of similarly situated individuals pray this Court enter judgment in its favor and against the Sanofi Defendants as follows:

a. awarding an amount to be determined at trial by jury that will fairly compensate Plaintiff, individually and on behalf of similarly situated individuals, for the harms suffered,

b. awarding Plaintiff, individually and on behalf of similarly situated individuals, punitive damages in an amount sufficient to deter the Sanofi Defendants and others from such conduct in the future, and

c. awarding Plaintiff, individually and on behalf of similarly situated individuals, their costs incurred herein, post-judgment interest, and for such other and further relief as the Court may deem just and proper under the circumstances.

WHEREFORE, Plaintiffs request on behalf of themselves and members of the Class that the Court enter an order or judgment against Defendants including the following:

a. a determination that this action may be maintained as a class action pursuant to Federal Rules of Civil Procedure Rule 23 and for an order certifying this case as a class action and appointing Plaintiff as class representatives as reflected above;

b. a declaration that Defendants' failure to disclose to consumers that Zantac produces unsafe levels of NDMA was unfair, deceptive, fraudulent, wrongful, and unlawful;

c. restitution for all purchases of Zantac by Plaintiff and the class, in an amount to be determined at trial;

d. disgorgement of the ill-gotten gains derived by Defendants from their misconduct;

e. compensatory damages caused by Defendants' unfair or deceptive practices, along with exemplary damages, to Plaintiffs and the class member for each violation;

f. punitive damages in an amount determined at trial sufficient to punish Defendants for their conduct and deter Defendants and others from like conduct;

g. pre-judgment and post-judgment interest at the maximum rate permitted by applicable law;

h. an order awarding Plaintiff and the class their attorney's fees, costs, and expenses incurred in connection with this action; and

i. such other and further relief as the Court deems just and proper.

JURY DEMAND

Plaintiff hereby demands a trial by jury, pursuant to Rule 38(b) of the Federal Rules of Civil Procedure, of all issues so triable.

Dated: November 22, 2019

Respectfully submitted,

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